

CLAIMS

METHOD OF ANTIGEN INCORPORATION INTO NEISSERIA BACTERIAL OUTER MEMBRANE VESICLES AND RESULTING VACCINE FORMULATIONS.

- 5 1. Method for antigen incorporation into bacterial outer membrane vesicles characterized by the formation of a non-covalent complex between these antigens and outer membrane proteins from gram-negative bacteria, being such complex generated by co-folding while maintaining intact the vesicle structure.
2. A method according to claim 1 wherein said outer membrane preparation is
10 obtained from gram-negative bacteria belonging to the *Neisseriaceae* family or to the *Bramhamella catarrhalis* species.
3. A method according to claim 2 wherein said outer membrane preparation is obtained from *Neisseria meningitidis* and *Neisseria lactamica*.
4. A method according to claims 1-3 wherein said protein antigen is of natural,
15 recombinant or synthetic origin.
5. A vaccine composition obtained according to claim 1, for its administration by parenteral or mucosal routes, characterized because comprises a complex formed by a protein antigen and a preparation of outer membrane proteins of gram-negative bacteria, being such complex generated by co-folding while
20 maintaining intact the vesicle structure in combination with pharmaceutically acceptable excipient.
6. A vaccine composition obtained according to claim 5 wherein said outer membrane preparation is obtained from gram-negatives bacteria belonging to the *Neisseriaceae* family or to the *Bramhamella catarrhalis* species.
- 25 7. A vaccine composition obtained according to claim 6 wherein said outer membrane preparation is obtained from *Neisseria meningitidis* and *Neisseria lactamica*.
8. A vaccine composition obtained according to claims 5-7 wherein said protein antigen is of natural, recombinant or synthetic origin.
- 30 9. A vaccine composition obtained according to claims 5-7 characterized for including also capsular bacterial polysaccharides.
10. A vaccine composition obtained according to claims 5-7 characterized for including also conjugated capsular bacterial polysaccharides.

11.A vaccine composition obtained according to claims 5-7 characterized for including also a nucleic acid as antigen

12.A vaccine composition obtained according to claims 5-11 for its therapeutic, or prophylactic use in humans.

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